

REMARKS

Claim amendments:

Claim 1 has been amended to recite that the guidewire is made from stainless steel or titanium. Support for the amendment can be found, for example, at page 6, lines 2-3. The use of stainless steel or titanium confers stiffness and torsional rigidity to the guidewire, further distinguishing the instant invention from the prior art.

Claims 2-9 were previously presented and are reiterated.

New Claims 9-15 have been added. These claims are drawn to substantially the same invention as Claims 1-9 but are of a different scope than these claims. Support for the amendments can be found throughout the short specification, particularly at pages 5-7.

Rejection under 35 U.S.C. § 102

Claims 1, 2, 4, and 5 were rejected under 35 U.S.C. § 102 as allegedly being anticipated by Muni *et al.*, U.S. Patent No. 6,190,332, made of record in the Office Action mailed November 19, 2003. Specifically, the Office Action asserted that “Muni discloses providing a wire (26) of a diameter greater than the maximal diameter . . . and reducing the diameter of the wire to less than maximal diameter . . . over substantially the entire length of the mandrel . . .” Page 3. In addition, Muni is asserted to disclose the step of center-less grinding. *Id.* For at least the following reasons, Applicants traverse the rejection.

Muni discloses that “[a] core wire previously made superelastic is subject to additional processing to remove superelasticity from a distal tip.” *E.g.*, column 2, lines 3-25; column 5, lines 50-61. Muni explicitly identifies NiTi alloy as the preferred material for the core wire, and further describes how to make a NiTi alloy superelastic by cold-working followed by heat treatment. Column 2, lines 8-12; column 5, line 53 – column 6, line 6. With the exception of claim 17, all claims in the Muni patent explicitly include the limitations “imparting superelasticity to the elongate body” and subsequently “removing superelasticity from the distal section of the elongate body” Claim 17 includes the limitations “providing means for imparting flexibility to the proximal and distal ends of the elongate body” and “providing means to provide shapeability to the distal end of the elongate body.”

Thus, in all cases, Muni imparts superelasticity or flexibility into at least the distal end of the core wire, followed by the removal of such superelasticity or flexibility from the distal section of the core wire.

In contrast, the instant invention recognizes that "there is a balance to the design of a guidewire which typically favors increased flexibility at the expense of torque control." Page 3, lines 22-23. However, the instant invention provides guidewires that overcome whipping problems and provide faithful torque transmission along their length. *See, e.g.*, page 4, lines 2-10; page 7, lines 3-6. Accordingly, the specification teaches the relationship between stiffness and strength and their effect on torque control. *See, e.g.*, pages 2-3. The specification identifies that stainless steel and titanium can be used to make the wire. Page 6, lines 2-3. Stainless steel and titanium possess a degree of stiffness and torsional rigidity. These metals are certainly not known to be superelastic and/or flexible. In fact, the use of stainless steel or titanium would presumably be incompatible with the goals of the Muni invention.

Applicants therefore submit that the instant invention is patentably distinct from that of Muni and that the rejection under 35 U.S.C. § 102 should be withdrawn.

Nonetheless, in the interest of expediting prosecution, Claim 1 has been amended to indicate that the guidewire is made from stainless steel or titanium. Applicants submit that the use of such material readily distinguishes the instant guidewire from that of Muni. For this additional reason, the rejection should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 3, 8, and 9 were rejected as being unpatentable over Muni (above) in view of Cornish (U.S. Pat. No. 6,132,389). The Office Action apparently considers that disclosure of the hydrophilic/lubricious coatings in Cornish corrects the defects in the Muni '332 patent, rendering obvious Claims 3, 8, and 9 of the instant application. Office Action at pages 3-4.

Claims 6 and 7 were also rejected under 35 U.S.C. § 103 over Muni in view of Applicants alleged admission that guidewires are known to be made by drawing wire from a spool and straightening the wire. Office Action at page 4.

Applicants traverse both obviousness rejections for essentially the same reasons as discussed above. Neither the disclosure of hydrophilic/lubricious coatings in the Cornish


reference nor the use of spooled and subsequently straightened wire, as described in Applicants' specification, corrects the defects in the Muni patent with respect to material stiffness and torsional rigidity and the stainless steel or titanium material of construction of the presently claimed guidewire. Therefore, neither combination of references renders the instant claims obvious and the rejection should be withdrawn.

CONCLUSIONS

In view of the above amendments and remarks, Applicants submit that the application is in full condition for allowance. Early notice to that effect is earnestly solicited. If a telephone conversation would help to expedite prosecution, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

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